

Message Text

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62

ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 /024 R

66612

DRAFTED BYGC DHEW/FDA/JRWEINROTH; MD

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DHEW/OIH/MACODDING

EUR/CE:DANDERSON (INFO)

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R 032214Z JUN 75

FM SECSTATE WASHDC

TO AMEMBASSY THE HAGUE

AMEMBASSY BONN

UNCLAS STATE 129376

E.O. 11652: N/A

TAGS: OGEN, EIND, TBIO, GW, NL

SUBJ: FDA REPRESENTATIVE PROVIDING TECHNICAL ASSISTANCE TO PHARMACEUTICAL MANUFACTURERS

1. FDA ADVISES THAT MR. FOSTER ACTON OF THE NEW YORK DISTRICT OFFICE WILL BE IN GERMANY AND HOLLAND JUNE 14-JULY 14, 1975.

2. THE PURPOSE WILL BE TO VISIT SIX PHARMACEUTICAL FIRMS RELATIVE TO NEW DRUG APPLICATIONS TO DETERMINE IF THE FIRM'S FACILITIES AND OPERA-

TIONS ARE IN CONCURRENCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS, AND TO REPORT ANY SIGNIFICANT DEVIATIONS WHICH WOULD HAVE AN ADVERSE EFFECT UPON THE SAFETY AND EFFICACY OF DRUGS BEING IMPORTED INTO THE UNITED STATES.

3. ITINERARY AS FOLLOWS:

JUNE 13, 1975 - DEPART WASHINGTON, D.C. FOR LUDWIGSHAFEN, WEST GERMANY.

JUNE 15-JUNE 18 - VISIT KNOLL

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JUNE 18 - TRAVEL LUDWIGSHAFEN TO FRANKFORT

JUNE 19 - JUNE 21 - VISIT HOECHST

JUNE 23 - TRAVEL TO BERLIN

JUNE 24-JUNE 26 - VISIT SCHERING

JUNE 27 - TRAVEL BERLIN TO OSS, NETHERLANDS.
JUNE 30-JULY 2 - VISIT DIOSYNTH
JULY 3 - TRAVEL OSS TO MAARSEN, NETHERLANDS
JULY 4-8 - VISIT ACF CHEMIEFARMA N.V.
JULY 9 - TRAVEL MAARSEN TO KATWIJK, NETHERLANDS
JULY 10-JULY 12 - VISIT B.V. CHEMISCHE
JULY 14 - DEPART NETHERLANDS FOR WASHINGTON, D.C.

3. ASSISTANCE OF EMBASSY WILL NOT BE REQUIRED.
INGERSOLL

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Margaret P. Grafeld
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